UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,562	06/24/2003	Michael N. Alekshun	PAZ-190	8041

959 7590 05/18/2007

LAHIVE & COCKFIELD, LLP
ONE POST OFFICE SQUARE
BOSTON, MA 02109-2127

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,562	ALEKSHUN ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *7-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Response and amendment filed 08 March 2007 to Office Action mailed 8 September 2006 is acknowledged and entered.

2. Recitation of U.S. Non-provisional Application and Attorney Docket Number in the header of each Page of the response and Claim Listing is greatly appreciated. However, please note that upon arrival at the USPTO, each response/filing is sorted according to claims, remarks, amendment, transmittal etc. for scanning coding and incorporation in to the Electronic File Wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded in the same application electronic file wrapper, and to further facilitate the prosecution; especially a telephonic conversation/interview with applicant/applicants' representative, it is suggested that the following information be recited in the header of each page for any filing/response/amendment:

a. Attorney Docket Number;
b. Filing date for said application (e.g., 17 November 2002);
c. First Applicant's name (e.g., Smith Jones et al.);
d. U.S. Non-Provisional Application Serial Number (e.g. 00/000,000);
e. Group Art Unit Number (e.g., 1657);
f. Date of Office Action being responded to (e.g., 27 August 2006);
g. Date of amendment/response (e.g., 27 April 2007); and
h. Examiner's name (e.g., Dr. Kailash C. Srivastava);

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

3. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/602,562), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

CLAIMS STATUS

4. Claims 1-52 are pending.

5. Claims 7-51 currently remain withdrawn.

6. Claims 1-6 and 52 are currently under examination.

Claim Rejections - 35 U.S.C. §112

7. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

8. Claims 1-6 and 52 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the written description requirement rejection of Claims 1-6 and 52 under 35 U.S.C. §112, first paragraph in the Office Action mailed 8 September 2006, citing case laws applicants argue that "an objective standard for determining compliance with the written description requirement under 35 U.S.C. §112, first paragraph, is whether the specification conveys with reasonable clarity to those killed in the art that as of the filing date sought, the applicant was in possession of the invention as now claimed". Applicants further argue, "Examiner has admitted, at page 5 of the Office Action that the specification describes, "the treatment of a microbial infection via administering a modulator of a transcription factor to an individual in need thereof". In the following paragraphs (See Remarks filed 08 March 2007, Page 9 Line 11 to Page 11, Line 20), Applicants provide citations to the specification of instant application and go on with a lengthy argument regarding:

a. description of methods to administer compounds that modulate the expression or activity of a microbial transcription factor to a subject to reduce the virulence of the microbe;
b. plethora of teachings on methods to generate the compounds and assay/ cell assay for effectiveness of said compounds;
c. methods to determine the modulation of transcription factor:
d. cell-free assays for screening inhibitors of the transcription factors;
e. suitability of testing claimed compounds' activity *in vitro*;
f. recitation of dosages given to mice in animal experimental models at the time of urinary tract infection in said mice;
g. application of a single subcutaneous dose of the inhibitor at the time of infection in pyelonephritis model;
h. compositions for the administration for a method of prophylaxis;

i. exemplary dosages of the inhibitor and routes of administering said dosages; and

j. *in vivo* working examples exemplifying the dosages described in the previous paragraphs regarding the composition for administration for a method of prophylaxis in the urinary tract infection animal model, wherein "mice were treated once at the time of infection" (See, e.g., Remarks, Page 11, Lines 8-9).

Applicants are absolutely correct that "an objective standard for determining compliance with the written description requirement under 35 U.S.C. §112, first paragraph, is whether the specification conveys with reasonable clarity to those killed in the art that as of the filing date sought, the applicant was in possession of the invention as now claimed". Applicants are also correct in arguing, "Examiner has admitted, at page 5 of the Office Action that the specification describes, "the treatment of a microbial infection via administering a modulator of a transcription factor to an individual in need thereof". Applicants indeed have with all clarity described in the specification a method to treat a microbial infection via administering a modulator of a transcription factor to an individual in need thereof.

Applicants are reminded, however, that as applicants have admitted on record, the claims are drawn to "a method to prevent infection, e.g., prostatitis or urinary tract infections of a subject by a microbe comprising administering a compound that modulates the activity or expression of a microbial transcription factor, wherein the modulation of said factor reduces the virulence of the microbe such that the infection is prevented" (see Remarks accompanying applicants amendment and response filed 8 March 2007,e.g., Page 8, Lines, 23-27). The tail end of this statement, however, is a description of the mechanism regarding how the infection is prevented, not a demonstration that the infection has actually been prevented through claimed administration of the claimed compound. Furthermore, the "interpretation that reduction of virulence is prevention" is only a mental step and a mental step to interpret/ consider result of an assay/method does not get a patentable weight. This is because same result may also be broadly interpreted as reduction in infection and then would be a treatment of infection as is stated in the above-cited remarks. Additionally, applicants repeatedly argue that "mice were treated at the time of infection and treatment prevented infection" (See e.g., Remarks accompanying response filed 08 March 2007, Page 10, Lines 9-11). If the treatment was given at the time of infection it is not prevention because the infection is already established, whereas prevention by definition is a proactive process and has to take place before the act of an event, in this case the "infection".

Furthermore, Applicants' arguments regarding the methods of screening, preparing and/ or assaying the compounds, or *in vitro* cellular assay methods, or the dosage regime, or the methods/ routes to administer the compound that inhibit the microbial transcription factor (See items a-j *supra*) are directed to subject matter that is not encompassed in the claimed invention in Claims 1-6 and 52. Thus, applicants have made arguments not regarding the claimed invention, rather regarding all the non-related unclaimed subject matter, whereas "the invention is the subject matter defined in the claims" (See *In re Priest*, 199USPQ 11*)*.

Applicants' arguments filed 08 March 2007 in regard to rejection to Claims 1-6 and 52 under 35 U.S.C. §112, first paragraph in the Office Action mailed 8 September 2006 have been carefully and fully considered, but as discussed *supra* they are not persuasive. Therefore, said rejection under 35 U.S.C. §112, first paragraph with regard to written description requirement is adhered to for the reasons of record at Pages 5-6 of the Office Action mailed 8 September 2006 and discussion presented *supra*.

CONCLUSION

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. For the aforementioned reasons, no claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

7 May 2007

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1657